



November 17, 2021

Via Email

Ethylene Oxide Commercial Sterilization Section 114 ICR Response
U.S. EPA Office of Air Quality Planning and Standards
Sector Policies and Programs Division, Fuels and Incineration Group
Mail Code E143-05
109 T.W. Alexander Drive
Research Triangle Park, NC 27711

Subject: Edwards Lifesciences' Response to Ethylene Oxide Commercial Sterilization
Section 114 Information Collection Request

Dear Ms. Spells:

On behalf of Edwards Lifesciences ("Edwards"), I am responding to the U.S. Environmental Protection Agency's ("EPA") September 13, 2021 Clean Air Act ("CAA") Section 114 Information Collection Request ("ICR") concerning emissions at ethylene oxide ("EtO") commercial sterilization facilities. This response is one of two submissions concerning the Edwards Añasco, PR facility. The other response contains Confidential Business Information ("CBI"); this response does not.

NOTE: An encrypted thumb drive with Edwards' CBI response has been sent via mail in accordance with the ICR instructions. The key for this thumb drive is 2\$XE3Evc.

As requested, our responses are included in the specific Excel Workbooks. With respect to our responses, Edwards makes the following general qualifications and objections to the ICR:

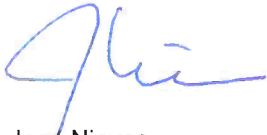
1. Edwards objects to the ICR to the extent it seeks privileged information, including all communications and documents that are protected from disclosure by the attorney client privilege, the work product doctrine, or other privileges.
2. Edwards objects to the ICR to the extent it seeks information or documents not within Edwards' possession, custody, or control. All responses are made on behalf of Edwards.
3. Edwards conducted a good faith review of its relevant documents to prepare the enclosed responses. However, Edwards did not search for every document or piece of information that may exist in the possession, custody, or control of any of Edwards' employees and agents where any such items are not included within the results of a reasonable search of records maintained in the ordinary course of business.
4. As a follow up to our email exchange with Ms. Charlene Spells, Office of Air and Radiation, dated November 8, 2021, Edwards is not required to complete, and did not complete, the Professional Engineer and Certified Industrial Hygiene certification blocks in the enclosed Excel Workbooks.
5. Edwards reserves the right to supplement and revise its response and reserves the right to assert to additional objections as it continues to evaluate the response.

Accordingly, subject to these qualifications and objections, Edwards provides the following enclosed materials:

- Excel Workbooks with responses:
 - Edwards_AñascoPR_EtO_114ICR_Main_NonCBI
 - Edwards_AñascoPR_EtO_114ICR_Sup3_NonCBI
- Various responsive non-CBI documents Bates stamped *EWAnascoPR000001NonCBI* to *EWAnascoPR000065NonCBI*

Please confirm receipt of this submission by emailing me at jose_nieves@edwards.com. Feel free to contact me by phone (787-229-5540) or email if you have any questions.

Sincerely,



Jose Nieves
Director, Facilities Engineering
Edwards Lifesciences
Añasco, Puerto Rico